REMARKS/ARGUMENTS

Prior to the present Office Action, claims 1-20 remain pending.

DECLARATION

The inventor declaration deemed to be defective because it did not include the proper language, namely: "I believe I am an original, ***first*** and joint inventor of the subject matter which is claimed and for which a patent is sought . . . " (Emphasis added). Therefore, a new executed Declaration with the proper language is submitted herewith.

DRAWINGS

As mentioned above, the reference signs 50, 52, 54a, 54b, and 56a are shown clearly in attached replacement Figure 3, which is believed to address the drawing rejection. An annotated sheet 3 showing the changes is also attached as required by the Examiner.

CLAIM REJECTIONS - 35 USC §103 – CLAIMS 1 AND 9

Claims 1, 2, 4-7, 9-12, 17, and 20 stand rejected under 35 U.S.C. section 103(a) as being unpatentable over Vilendrer (U.S. 5,670,708) in view of Dunkelman, et al (U.S. 5,792,603). Applicants respectfully assert that the present invention as claimed is not obvious over Vilendrer in combination with Dunkelman, et al., and further that the combination is not suggested by either reference.

Vilendrer discloses an intravascular prosthesis fatigue tester which is best seen in cross-section in Figure 6. In the description in column 2, lines 10-51, the fatigue tester utilizes a fluid conduit that includes "at least one elastic simulated arterial/venous tube which approximates the geometry of a healthy human arterial/venous vessel." The prosthesis is placed within the tube which is pressurized with a temperature controlled fluid and the radial dilation thereof is measured with a compliance transducer. In column 4, line 25, the tube is said to be made from a "flexible latex rubber."

The system disclosed in Vilendrer is manufactured by Endura-Tec Systems Corporation of Minnesota, and has been used for a number of years in the testing of such prostheses. Indeed, such systems were described in the background of present application at the bottom of page 3. The systems only utilize synthetic tubes as the conduits for testing the prostheses. There is no suggestion in Vilendrer to replace the four latex tubes in the illustrated device with anything but latex, and as mentioned in the background of the present application at page 3, line 17, such prior art systems typically use compliant tubes of latex or silicone. One obvious reason for utilizing artificial tubes is the ability to easily control and therefore rely on the physical characteristics of the tubes.

Indeed, the examiner admits that Vilendrer does not disclose an animal tissue tube, and cites Dunkelman, et al. to supply such a missing element in the rejection of claims 1 and 9 and their dependents. However, Dunkelman, et al. also do not disclose an animal tissue tube as a pressurized conduit for compliance testing. Applicants respectfully object to the Examiner's citation of the Abstract of Dunkelman, et al. as disclosing the use of an "animal tissue tube." There simply is no such disclosure. Applicants note that in the present claims 1 and 9 it is the tube within which the stent or stented graft is mounted that is made of animal tissue.

In one embodiment, Dunkelman, et al. disclose a system for sterilizing, seeding, culturing, storing, shipping, and testing vascular grafts that includes a treatment chamber 14 housing an expandable tube 32 upon which may be placed a vascular graft scaffolding 26. The tube 32 "may be comprised of any suitable elastomeric material, such as PET or silicone angioplasty balloons, which is capable of expanding and contracting." (col. 3, lines 57-66) Clips or grommets are used to hold the vascular graft scaffolding onto the exterior of the tube. FIG. 4 discloses an alternative embodiment where the treatment chamber 46 houses a porous tube 48 (of any suitable rigid material, such as Teflon, PVC, polycarbonate, or stainless steel) upon which may be placed the vascular graft scaffolding 26. Fluid flow through the porous material will place a varying radial stress on vascular graft scaffolding 26. In a third embodiment, shown in Fig. 5 the vascular graft 84 is connected directly to treatment chamber cap 78 using luer 80 or

other appropriate connecting means. In each of these examples, the graft is caused to expand and contract during processing to simulate physiologic pressures/conditions.

Nowhere in Dunkelman, et al. is there disclosure or a suggestion to use animal tissue as the various tubes on which the vascular graft mounts, and therefore the reference adds nothing to Vilendrer to render claim 1 obvious.

Claim 1 of the present application provides a compliance testing assembly which has an animal tissue tube and a pre-tester including fixtures adapted to sealingly couple to the free ends of the tube and having a fluid supply in communication with at least one of the fixtures and the tube lumen. A stent or stent graft is positioned within the animal tissue tube which can be subjected to fluid flow for testing the compliance of the prosthesis within the tube. Vilendrer does not disclose the use of an animal tissue tube and does not suggest substituting one for the latex tube disclosed. One of skill in the art would not be motivated to utilize an animal tissue tube for the flow or pulsatile testing because Dunkelman, et al. utilize synthetic (i.e., PET, silicone, Teflon, PVC, polycarbonate, or stainless steel) tubes for their flow testing.

Therefore, claim 1 and all claims dependent therefrom are believed to be patentable over the cited art.

Likewise, a method as in claim 9 that uses an animal tissue tube to test the compliance of a stent or stented graft is not taught by Vilendrer alone or in combination with Dunkelman, et al. Claim 9 provides a method of testing the compliance of a stent or stent graft including using an animal tissue tube and flowing a fluid therethrough. As stated above, Vilendrer does not disclose or suggest the use of an animal tissue tube, and the combination with Dunkelman, et al. is insufficient and unwarranted. Accordingly, claims 9-16 are believed allowable over the cited references.

Moreover, the combination of the two references is not suggested by either. First, there is no mention of modifying the tester tubes in Vilendrer to be anything but latex. Conversely, Dunkelman, et al. do not suggest using any materials other than synthetic for the test tubes. In other words, there would be no motivation to combine the two references. Accordingly, claims 1

and 9 and their dependents are believed allowable over the cited references.

CLAIM REJECTIONS - 35 USC §103 – CLAIM 17

Claims 17 and 20 stand rejected under 35 U.S.C. section 103(a) as being unpatentable over Vilendrer (U.S. 5,670,708) in view of Glenn, et al (www.enduratec.com/papers/nitinol).

Claim 17 does not specify the use of an animal tissue tube for testing the compliance of stents or stent grafts, but instead recites the methodology of utilizing a pre-tester before a tester. The pre-tester tube is pressurized to pulsatile pressures found in the human vascular system and the exterior diameter thereof is measured and recorded. Subsequently, the stent or stent graft is placed in a tester tube and the tube pressurized at a pulsed rate at pressures controlled based on the recorded data from the pre-tester.

As noted by the Examiner, Vilendrer does not disclose the use of a pre-tester including a pre-tester tube, and in general does not disclose any method or means for calibrating the final tester apparatus. Instead, as stated in column 2, lines 42-51 (and later, in column 6, lines 4-54), the tester disclosed in Vilendrer utilizes a feedback loop including a transducer for measuring the tester tube's radial dilation and a microprocessor-based controller. A signal corresponding to the dilation of the tube may be used to ensure that the test is run at a specific dilation range. There is no separate pre-tester and tester, and the examiner errs in lumping the two functions together (e.g., with the use of the term "tester/pre-tester"). In claim 17, these are two separate method steps, which is clearly explained in the present application.

There is no mention in the rejects of calling the two as "tester/pretester" separate method steps

The paper on the Enduratec system by Glenn, et al. merely discloses a pre-testing step on the same machine used to test the stents. That is, the paper states:

> Before loading the stents into the tubes, the machine was "pre-tested" at a cycle rate of 45 Hz with systolic and diastolic average pressures of 250 and -100 mm hg, respectively. The empty tubes measured 4.5%-5.5%. The "pressure pulse", the difference between the systolic and diastolic pressures, averaged 350 mm hg, more than 8.5 times that seen in a human.

The stents were then mounted into the tubes, and fluid pulsed through the tubes:

check pages 11-12 of the Office Action

After deploying the stents, the same settings as the "pre-test" were maintained, resulting in compliance between 1.0%-1.5%

There is no mention of measuring and recording the exterior diameter of the pre-tester tube at different pressures, and then measuring the exterior diameter of the tester tube while controlling the fluid pressure based on the recorded data, as in claim 17. Instead, the Enduratec system merely pressurizes the "tester" tube at the same pressures ("settings") as in the pre-test. This is not the same as, and does not render obvious, the methodology of claim 17 where the fluid pressure within the test tube is controlled based on diametric measurements of a pre-test tube. Indeed, the pressures in the test run could be quite different than pressures in the pre-test run (see specification, page 9 bottom) which states, "the pulsed fluid pressures within the tubes are adjusted to maintain the tube expansion the same as that recorded in the pre-test. In this way, expansion of the stents or stented grafts during the test is maintained at the magnitude of that in the pre-test, which simulates the conditions *in vivo*."

Therefore, applicants asserted that at least for the reasons discussed above claim 17 and its dependent claims 18-20 are allowable over Vilendrer in combination with Glenn, et al.

In view of the foregoing remarks, Applicants assert that claim 1-20 are allowable over the cited references. If there is any further hindrance to allowance of the claims, the Examiner is encouraged to contact the undersigned by telephone.

Respectfully submitted,

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